



NDA 18-519/S-015

Baxter Healthcare Corporation
Attention: Marcia Marconi
Vice President, Regulatory Affairs
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated November 28, 2000, received November 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Irrigating Solution G (PL 325).

We acknowledge receipt of your submissions dated February 14, and March 9, 2001.

This supplemental new drug application provides for addition of a Geriatric Use subsection in the labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 9, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Evelyn R. Farinas, R.Ph., M.G.A., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Susan Allen, M.D.

Director

Division of Reproductive and Urologic Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research